

REMARKS

This Response is submitted in reply to the non-final Office Action mailed on March 30, 2011. No fees are due herewith this Response. The Director is authorized to charge any fees that may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 3712036-00755 on the account statement.

Claims 1-11 and 13-14 are pending in the application. Claims 8-11 and 13-14 were previously withdrawn, and Claim 12 was previously canceled without prejudice or disclaimer. In the Office Action, Claims 1-7 are rejected under 35 U.S.C. §102 and 35 U.S.C. §103. In response, Claim 1 has been amended. The amendments do not add new matter and are supported in the specification at, for example, page 7, lines 2-4. In view of the amendments and/or for at least the reasons set forth below, Applicants respectfully request that the rejections be withdrawn.

In the Office Action, Claims 1 and 4-7 are rejected under 35 U.S.C. §102(b) as being anticipated by "Storage Stability of Vegetables Fermented with pH Control," Journal of Food Science 1983, Vol. 48, p. 975-981 to Fleming et al. ("*Fleming*"). Applicants respectfully submit that *Fleming* is deficient with respect to the present claims.

Currently amended independent Claim 1 recites, in part, a liquid product that is water- or milk-based and comprises living microorganisms, the liquid product having a pH from about 4 to about 7.5 and shelf-life of at least 1 month at 10°C, and wherein the liquid product is free of carbohydrates that can be metabolized by the microorganisms. The amendments do not add new matter and are supported by the specification at, for example, page 7, lines 2-4. As is described in detail in the specification, the presently claimed products are shelf-stable because the microorganisms contained therein are able to survive for several months at room temperatures due to their inability to metabolize nutrients contained in the product. See, specification, Abstract. Indeed, the fact that many probiotic bacteria possess an anaerobic metabolism imposes specific technical requirements on all process and product levels between a starting culture and a consumable product suitable to deliver said bacterium in sufficiently high concentration to a human or animal. See, specification, lines 31-34. Further, the mere fact that living bacteria are metabolically active--even at chilled temperatures--imposes problems: ingestible carriers of

probiotics often sustain degradation by the bacterial activity, which may render the carrier completely unpalatable. See, specification, page 1, line 36-page 2, line 2.

One way of delivering a probiotic is the preparation of a material, which was fermented by the probiotic. This is the case, for example, with yoghurts that were obtained from fermenting milk with micro-organisms. An advantage of these products is that they are relatively stable when chilled, due to the low pH of the product after fermentation. However, the acid produced by the fermenting activity of the probiotic does not correspond to every consumer's taste. In addition, these products still have to be chilled. See, specification, page 2, lines 21-27. Thus, prior art products having microorganisms may suffer from a number of deficiencies including, for example, the inability to provide a sufficient concentration of the microorganism to the subject, or unpalatability.

In contrast, however, Applicants have surprisingly found that providing microorganisms in a product that does not contain carbohydrates that may be digested by the microorganism results in a product that is shelf-stable for extended periods of time and provides a sufficient amount of microorganisms to the subject. As is further described in the specification, the products according to the present disclosure may be fermented products, which are obtained, for example, by fermenting a medium, heat treating or pasteurizing the medium to reduce bacterial load, and, at the same time, kill the fermenting bacteria. Then the fermented products could be supplemented with a micro-organism, which will not further grow on the fermented medium. For example, the products may be a yoghurt, which is heat-treated and to which micro-organisms which are not able to grow on the fermented, heat-treated product are added, in order to obtain products that fulfill the features of the present claims. See, specification, page 6, lines 20-32. In contrast, Applicants respectfully submit that *Fleming* fails to disclose or suggest each and every element of the present claims.

For example, *Fleming* fails to disclose or suggest a liquid product that is water- or milk-based and comprises living microorganisms, the liquid product having a pH from about 4 to about 7.5 and shelf-life of at least 1 month at 10°C, and wherein the liquid product is free of carbohydrates that can be metabolized by the microorganisms as required, in part, by the present claims. Instead, *Fleming* is entirely directed to storage of a vegetable product in sealed jars at about 24°C having all fermentable sugars removed from the vegetables during fermentation and

stored at a pH of 3.8 or below. See, *Fleming*, Abstract. Accordingly, not only does *Fleming* fail to disclose or suggest a liquid product, since a vegetable product is not a liquid product, but *Fleming* also fails to disclose or suggest a liquid product having a pH from about 4 to about 7.5.

The Patent Office states that “the pH of the product at the beginning of storage is 4 or higher (pH 4.5).” See, Office Action, page 3, lines 15-17. However, the potion of *Fleming* cited by the Patent Office simply states that “[t]he brine contained 5% NaCl and 0.1% acetic acid adjusted to pH 4.5 with NaOH.” As mentioned above, however, the brine solution is not the product of *Fleming* – the products are vegetables. Further, the vegetables have the fermentable sugars removed therefrom, not the brine. As such, it is not clear whether the Patent Office intends for the vegetables to be the product, or the brine solution to be the product. Either way, however, *Fleming* does not disclose or suggest a liquid product that is water- or milk-based and comprises living microorganisms, the liquid product having a pH from about 4 to about 7.5, and wherein the liquid product is free of carbohydrates that can be metabolised by the microorganisms as required, in part, by the present claims.

Further, anticipation is a factual determination that “requires the presence in a single prior art disclosure of each and every element of a claimed invention.” *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747 (Fed. Cir. 1987) (emphasis added). Federal Circuit decisions have repeatedly emphasized the notion that anticipation cannot be found where less than all elements of a claimed invention are set forth in a reference. See, e.g., *Transclean Corp. v. Bridgewood Services, Inc.*, 290 F.3d 1364, 1370 (Fed. Cir. 2002). As such, a reference must clearly disclose each and every limitation of the claimed invention before anticipation may be found. Because *Fleming* fails to disclose or suggest each and every element of the present claims, *Fleming* fails to anticipate the present claims.

Accordingly, Applicant respectfully requests that the anticipation rejections with respect to Claims 1 and 4-7 be reconsidered and the rejections be withdrawn.

In the Office Action, Claims 1-7 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Fleming* and WO 00/53202 to Reniero et al. (“*Reniero*”). Applicants respectfully submit that the cited references are deficient with respect to the present claims.

As discussed above, currently amended independent Claim 1 recites, in part, a liquid product that is water- or milk-based and comprises living microorganisms, the liquid product

having a pH from about 4 to about 7.5 and shelf-life of at least 1 month at 10°C, and wherein the liquid product is free of carbohydrates that can be metabolized by the microorganisms. The amendments do not add new matter and are supported by the specification at, for example, page 7, lines 2-4. As is further discussed above, *Fleming* fails to disclose or suggest a liquid product that is water- or milk-based and comprises living microorganisms, the liquid product having a pH from about 4 to about 7.5 and shelf-life of at least 1 month at 10°C, and wherein the liquid product is free of carbohydrates that can be metabolized by the microorganisms as required, in part, by the present claims. Instead, *Fleming* is entirely directed to storage of a vegetable product in sealed jars at about 24°C having all fermentable sugars removed from the vegetables during fermentation and stored at a pH of 3.8 or below. See, *Fleming*, Abstract. Accordingly, not only does *Fleming* fail to disclose or suggest a liquid product, since a vegetable product is not a liquid product, but *Fleming* also fails to disclose or suggest a liquid product having a pH from about 4 to about 7.5.

The Patent Office admits that “*Reniero et al.* do not teach the liquid product (cereal drink) is free of carbohydrates that can be metabolized by the *Lactobacillus*.” See, non-final Office Action dated October 28, 2010, page 6, lines 1-2. Instead, *Reniero* is entirely directed to the prevention of diarrhea brought about by rotaviruses and pathogenic bacteria. See, *Reniero*, Abstract. Indeed, *Reniero* expressly discloses that the microorganisms (e.g., lactic acid bacterium) used in the compositions must be capable of growing in the presence of bile salts in a composition of up to about 0.4% and may essentially prevent invasion of epithelial cells by rotaviruses. See, *Reniero*, page 3, lines 27-31. *Reniero* refers to liquid products comprising a strain such as *Lactobacillus paracasei* CNCM I-2116, which may be grown, for example, in tomato powder rehydrated with distilled water and used as inoculum.

Tomatoes contain different kinds of carbohydrates. Storage is performed at 10°C for up to 30 days employing a medium comprising 2% wheat flour, 3% rice flour and 3% sucrose, i.e., a medium containing different kinds of carbohydrates in high amounts. *Reniero* clearly discloses storage of such a liquid product with added carbohydrates only. It is neither disclosed nor suggested that long term storage at high temperatures of a liquid product containing said strain may be performed in case metabolized carbohydrates are omitted. As such, it is clear that *Reniero* merely discloses that “Lactic acid bacteria are utilized as fermenting agents for the

preservation of food taking benefit of a low pH and the action of fermentation products generated during the fermentative activity thereof to inhibit the growth of spoilage bacteria. To this end, lactic acid bacteria have been used for preparing a variety of different foodstuff such as cheese, yogurt and other fermented dairy products from milk.” See, *Reniero*, page 1, lines 17-21.

At no place in the disclosures do either *Fleming* or *Reniero* disclose or suggest a liquid product that is water- or milk-based and comprises living microorganisms, the liquid product having a pH from about 4 to about 7.5 and shelf-life of at least 1 month at 10°C, and wherein the liquid product is free of carbohydrates that can be metabolized by the microorganisms as required, in part, by the present claims.

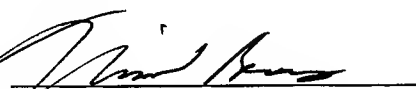
For at least the reasons discussed above, Applicants respectfully submit that Claims 1-7 are novel, nonobvious and distinguishable from the cited reference.

Accordingly, Applicant respectfully requests that the obviousness rejections with respect to Claims 1-7 be reconsidered and the rejections be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly request an early allowance of the same. In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

K&L GATES LLP

BY 

Michael A. Beckett
Reg. No. 48,127
Customer No. 29157
Telephone No. 312-781-6011

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